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Sylvan N. Goldman Center

Oklahoma Blood Institute

A Not-for-Profit Regional Blood Center

1001 N. Lincoln Blvd., Oklahoma City, OK 73104

(405) 297-5700 www.obl.org

September 17, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, RM 1061
Rockville, MD 20852

RE: Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components

Dear Document Manager,

The Oklahoma Blood Institute (OBI), Sylvan N. Goldman Center, Oklahoma Blood Institute, 1001 North Lincoln Boulevard, Oklahoma City, Oklahoma 73104-3299, US License Number 0766-001, Registration Number 1626009, is submitting this letter to request that the agency consider revision of Appendix 2: Donor History Questionnaire User Brochure located in the "Draft Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components."

Specifically, in the section marked **Questions to detect donors at risk for HIV group O** the phrase "Blood collection agencies utilizing an HIV antibody test that has been approved by the FDA to include a claim for detection of Group O viruses may delete questions 47 and 48..." We suggest deleting the term "antibody" from this sentence. The revised text would then read: "Blood collection agencies utilizing an HIV test that has been approved by the FDA to include a claim for detection of Group O viruses may delete questions 47 and 48..." This change would allow facilities utilizing a Nucleic Acid Test approved by the FDA to include a claim for detection of Group O viruses to also delete questions 47 and 48 on the Acceptable Full-Length Donor History Questionnaire.

Although we are aware that the open comment period for this document has passed, we know that the agency always welcomes comments from the industry. Thank you for reviewing these comments. If you have any questions, please feel free to contact me by phone at 405-297-5758 or by e-mail at CMooney@OBI.ORG.

Respectfully,

Charles Mooney, MBA, MS, MT(ASCP)SBB
Vice President, Ancillary Services
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